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INTELLECTUAL PROPERTY / TECHNOLOGY LAW  
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EXAMINER

EPPERSON, JON D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 08/27/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/677,152

Applicant(s)

GALLO ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1627 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The fax number is (703) 308-4315. A fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Joseph McKane, Supervisory Patent Examiner, at (703) 308-4537. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Please note that in preparing this Restriction Requirement the examiner noted a problem with claims 51-56. Claims 51-56 refer to the "method of claim 52"; however, claims 51 and 52 should not depend on a later claim or the same claim, respectively. As a result, the examiner has interpreted claims 51-56 to read "The method of claim 50" instead of "The method of claim 52." It would assist the further examination of this case on the merits if applicant could correct and/or address this problem in the Response to this action.

2. Please note that in preparing this Restriction Requirement the examiner noted a problem with claim 75. Claims 75 refer to the sequence "58-56." The examiner has interpreted claims 75 to read "48-56" instead. It would assist the further examination of this case on the merits if applicant could correct and/or address this problem in the Response to this action.

### *Election/Restriction*

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-7 (in part), 8-11 drawn to a product described as an isolated protein or peptide of claim 1 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 41-54, 45-54, 47-53, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-58, 48-56 (see claim 7), classified in class 514, subclass 2; class 930, subclass 30.
- II. Claims 1, 2, 4, 5, 7 (in part), 8-11 drawn to a product described as an isolated protein or peptide of claim 1 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 46-65 (see claim 7), classified in class 514, subclass 2; class 930, subclass 30.
- III. Claims 1, 2, 4, 5, 7-9 (in part), 10, 11 drawn to a product described as an isolated protein or peptide of claim 1 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 58-145 (see claim 7), classified in class 514, subclass 2; class 930, subclass 30.
- IV. Claims 1, 4, 7 (in part), 8-11 drawn to a product described as an isolated protein or peptide of claim 1 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 7-40 (see claim 7), classified in class 514, subclass 2; class 930, subclass 30.
- V. Claims 1, 12, and 14(a) drawn to a product described as an isolated protein or peptide of claim 12 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 45-57 (SEQ ID NO:6) linked at the C-terminus via a

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- peptide bond to the N-terminus of  $\beta$ -hCG amino acids 109-119 (SEQ ID NO:7)", classified in class 514, subclass 2; class 930, subclass 30.
- VI. Claims 1, 12, and 14(b) drawn to a product described as an isolated protein or peptide of claim 12 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 110-119 (SEQ ID NO:27) linked at the C-terminus via a peptide bond to the N-terminus of  $\beta$ -hCG amino acids 45-57 (SEQ ID NO:6)", classified in class 514, subclass 2; class 930, subclass 30.
- VII. Claims 1, 12, and 14(c) drawn to a product described as an isolated protein or peptide of claim 12 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 47-57 (SEQ ID NO:28) linked at the C-terminus via a peptide bond to the N-terminus of  $\beta$ -hCG amino acids 108-119 (SEQ ID NO:29)", classified in class 514, subclass 2; class 930, subclass 30.
- VIII. Claims 1, 12 and 13 drawn to a product described as an isolated protein or peptide of claim 12 wherein "the  $\beta$ -hCG amino acid sequences joined via a peptide bond to a protein or peptide sequence of a protein or peptide different from  $\beta$ -hCG", classified in class 514, subclass 2; class 930, subclass 30.
- IX. Claims 15-17, 18 (in part), 19 drawn to a product described as a circularized protein or peptide of claim 15 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 41-54, 45-54, 47-53, 45-57,

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41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-57, 47-56, 47-58, 48-56 (see claim 18), classified in class 514, subclass 2; class 930, subclass 30; class 514 subclass 9.

X. Claims 15-17, 18 (in part) drawn to a product described as a circularized protein or peptide of claim 15 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 46-65 (see claim 18), classified in class 514, subclass 2; class 930, subclass 30; class 514 subclass 9.

XI. Claims 15-17, 18 (in part) drawn to a product described as a circularized protein or peptide of claim 15 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 109-119, 58-145, 109-145 (see claim 18), classified in class 514, subclass 2; class 930, subclass 30; class 514 subclass 9.

XII. Claims 15-17, 18 (in part) drawn to a product described as an isolated protein or peptide of claim 1 wherein the  $\beta$ -hCG segment is selected from the group consisting of ... 7-40 (see claim 18), classified in class 514, subclass 2; class 930, subclass 30.

XIII. Claims 15, 20, and 21 drawn to a product described as a circularized protein or peptide of claim 20 wherein "the first the portion consists of  $\beta$ -hCG amino acid numbers 45-57 (SEQ ID NO:6); ... [etc]" (see claim 21), classified in class 514, subclass 2; class 930, subclass 30.



XIV.

Claims 22-28, 29 (in part), 30, 31, 32, 33 drawn to a product described as an isolated protein or peptide of claim 22 wherein at least one portion of the sequence consists of amino acid numbers ... 41-54, 45-54, 47-53, 45-57, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-57, 47-56, 47-58, 48-56 (see claim 29), classified in class 514, subclass 2; class 930, subclass 30.

XV.

Claims 22-27, 29 (in part), 32 drawn to a product described as an isolated protein or peptide of claim 22 wherein at least one portion of the sequence consists of amino acid numbers ... 46-65 (see claim 29), classified in class 514, subclass 2; class 930, subclass 30.

XVI.

Claims 22-27, 29 (in part), 32 drawn to a product described as an isolated protein or peptide of claim 22 wherein at least one portion of the sequence consists of amino acid numbers ... 109-119, 58-145, 109-145 (see claim 29), classified in class 514, subclass 2; class 930, subclass 30.

XVII.

Claims 22-24, 26, 29 (in part), 32 drawn to a product described as an isolated protein or peptide of claim 22 wherein at least one portion of the sequence consists of amino acid numbers ... 7-40 (see claim 29), classified in class 514, subclass 2; class 930, subclass 30.

XVIII.

Claims 34-38 drawn to a product described as a circularized protein or peptide, classified in class 514, subclass 2; class 930, subclass 30; class 514 subclass 9.

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XIX.

Claim 39 (in part) drawn to a product described as an isolated protein or peptide wherein at least one portion of the sequence consists of amino acid numbers ... 41-54, 45-54, 47-53, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-56, 47-58, 48-56 (see claim 39), classified in class 514, subclass 2; class 930, subclass 30.

XX.

Claims 39 (in part) drawn to a product described as an isolated protein or peptide wherein at least one portion of the sequence consists of amino acid numbers ... 46-65 (see claim 39), classified in class 514, subclass 2; class 930, subclass 30.

XXI.

Claim 39 (in part) drawn to a product described as an isolated protein or peptide wherein at least one portion of the sequence consists of amino acid numbers ... 58-145 (see claim 39), classified in class 514, subclass 2; class 930, subclass 30.

XXII.

Claim 39 (in part) drawn to a product described as an isolated protein or peptide wherein at least one portion of the sequence consists of amino acid numbers ... 7-40 (see claim 39), classified in class 514, subclass 2; class 930, subclass 30.

XXIII.

Claims 40-41 drawn to a composition comprising one or more first components of a second composition comprising a sample of native hCG or native  $\beta$ -hCG, classified in class 514, subclass 2; class 514, subclass 21.



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- XXIV. Claims 42-49 drawn to a method for producing a composition, classified in class 514, subclass 2.
- XXV. Claims 50-55, 56 (in part) drawn the method of claim 50 wherein the portion of the  $\beta$ -hCG amino acid sequence is selected from the group consisting of ... 41-54, 45-54, 47-53, 45-57, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-55, 47-56, 47-58, 48-56 (see claim 56), classified in class 514, subclass 2.
- XXVI. Claims 50-52, 54, 56 (in part) drawn to the method of claim 50 wherein the portion of the  $\beta$ -hCG amino acid sequence is selected from the group consisting of ... 46-65 (see claim 56), classified in class 514, subclass 2.
- XXVII. Claims 50-52, 54, 56 (in part) drawn to the method of claim 50 wherein the portion of the  $\beta$ -hCG amino acid sequence is selected from the group consisting of ... 48-145, 58-145 (see claim 56), classified in class 514, subclass 2; class 424, subclass 188.1.
- XXVIII. Claims 50, 51, 54, 56 (in part) drawn to the method of claim 50 wherein the portion of the  $\beta$ -hCG amino acid sequence is selected from the group consisting of ... 7-40 (see claim 56), classified in class 514, subclass 2; class 424, subclass 188.1.
- XXIX. Claims 50, 57 and 58(a) drawn to the method of claim 57 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 45-57 (SEQ ID NO:6) linked

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at the C-terminus via a peptide bond to the N-terminus of  $\beta$ -hCG amino acids 109-119 (SEQ ID NO:7)", classified in class 514, subclass 2; class 424, subclass 188.1.

XXX.

Claims 50, 57 and 58(b) drawn to the method of claim 57 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 110-119 (SEQ ID NO:27) linked at the C-terminus via a peptide bond to the N-terminus of  $\beta$ -hCG amino acids 45-57 (SEQ ID NO:6)", classified in class 514, subclass 2; class 424, subclass 188.1.

XXXI.

Claims 50, 57 and 58(c) drawn to the method of claim 57 wherein the amino acid sequence of the protein or peptide is selected from the group consisting of " $\beta$ -hCG amino acids 47-57 (SEQ ID NO:28) linked at the C-terminus via a peptide bond to the N-terminus of  $\beta$ -hCG amino acids 108-119 (SEQ ID NO:29)", classified in class 514, subclass 2; class 424, subclass 188.1.

XXXII

Claims 59-62, 63 (in part), 64 drawn to the method of claim 59 wherein the at least one portion of the sequence is selected from the group consisting of ... 41-54, 45-54, 47-53, 45-57, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-57, 47-56, 47-58, 48-56 (see claim 18), classified in class 514, subclass 2; class 424, subclass 188.1.

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- XXXIII. Claims 59-62, 63 (in part) drawn to the method of claim 59 wherein the at least one portion of the sequence is selected from the group consisting of ... 46-65 (see claim 18), classified in class 514, subclass 2; class 424, subclass 188.1.
- XXXIV. Claims 59-62, 63 (in part) drawn to the method of claim 59 wherein the at least one portion of the sequence is selected from the group consisting of ... 109-119, 58-145, 109-145 (see claim 18), classified in class 514, subclass 2; class 424, subclass 188.1.
- XXXV. Claims 59-62, 63 (in part) drawn to the method of claim 59 wherein the at least one portion of the sequence is selected from the group consisting of ... 7-40 (see claim 18), classified in class X, subclass Y.
- XXXVI. Claims 65, 66 (in part), 67 drawn to the method of claim 65 wherein the at least one portion of the sequence is selected from the group consisting of ... 41-54, 45-54, 47-53, 45-57, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-54, 47-57, 47-55, 47-56, 47-58, 48-56 (see claim 18), classified in class 514, subclass 2; class 424, subclass 188.1.
- XXXVII. Claims 65, 66 (in part) drawn to the method of claim 65 wherein the at least one portion of the sequence is selected from the group consisting of ... 46-65 (see claim 18), classified in class 514, subclass 2.
- XXXVIII. Claims 65, 66 (in part) drawn to the method of claim 65 wherein the at least one portion of the sequence is selected from the group consisting

of ... 109-119, 58-145, 109-145 (see claim 18), classified in class 514, subclass 2; class 424, subclass 188.1.

XXXIX. Claims 65, 66 (in part) drawn to the method of claim 65 wherein the at least one portion of the sequence is selected from the group consisting of ... 7-40 (see claim 18), classified in class 514, subclass 2.

XXXX. Claims 68-70 drawn to a method of treating or preventing a condition consisting of HIV infection, cancer, wasting, and hematopoietic deficiency, classified in class 514, subclass 2; class 424, subclass 188.1.

XXXXI. Claims 71-73 drawn to a second method of treating or preventing a condition consisting of HIV infection, cancer, wasting, and hematopoietic deficiency, classified in class 514, subclass 2.

XXXXII. Claim 74 drawn to a method of screening a preparation comprising hCG or  $\beta$ -hCG or a fraction of an hCG or  $\beta$ -hCG preparation ... for at least one therapeutic effect selected from the group of HIV infection, cancer, wasting, and hematopoietic deficiency, classified in class 514, subclass 2; class 424, subclass 188.1.

XXXXIII. Claims 75 (in part) drawn to a pharmaceutical composition wherein a therapeutically effective amount of a purified protein or peptide comprising an amino acid sequence consisting of a sequence selected from the group consisting of ... 41-54, 45-54, 47-53, 45-57, 41-53, 42-53, 43-53, 44-53, 44-57, 45-53, 46-53, 45-54, 45-55, 45-56, 45-58, 47-

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54, 47-56, 47-58, 48-56 (see claim 18), classified in class 514, subclass 2; class 424, subclass 499.

XXXXIV. Claims 75 (in part) drawn to a pharmaceutical composition wherein a therapeutically effective amount of a purified protein or peptide comprising an amino acid sequence consisting of a sequence selected from the group consisting of ... 46-65 (see claim 18), classified in class 514, subclass 2; class 424, subclass 499.

XXXXV. Claims 75 (in part) drawn to a pharmaceutical composition wherein a therapeutically effective amount of a purified protein or peptide comprising an amino acid sequence consisting of a sequence selected from the group consisting of ... 109-119, 58-145, 109-145 (see claim 18), classified in class 514, subclass 2; class 424, subclass 499.

XXXXVI. Claims 75 (in part) drawn to a pharmaceutical composition wherein a therapeutically effective amount of a purified protein or peptide comprising an amino acid sequence consisting of a sequence selected from the group consisting of ... 7-40 (see claim 18), classified in class 514, subclass 2; class 424, subclass 499.

XXXXVII-LIV. Claims 76-83 drawn to pharmaceutical compositions comprising the protein or peptide of claim 76 (Group XXXXVII), claim 77 (Group XXXXVIII), claim 78 (Group XXXXIX), claim 79 (Group L), claim 80 (Group LI), claim 81 (Group LII), claim 82 (Group LIII), claim 83

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(Group LIV) classified in class 514, subclass 2; class 424, subclass  
499.

4. The inventions are distinct, each from the other because of the following reasons:

5. Claim 1 link(s) groups I-IV. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Claim 12 link(s) groups V-VII. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 12. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such



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claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

7. Claim 15 link(s) groups IX-XII. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Claim 22 link(s) groups XIV-XVII. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 22. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any



claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

9. Claim 50 link(s) groups XXV-XXVII. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 50. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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10. Claim 57 link(s) groups XXIX-XXXI. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 57. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

11. Claim 59 link(s) groups XXXII-XXXV. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 59. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

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requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

12. Claim 65 link(s) groups XXXVI-XXXIX. The restriction requirement among the linked groups is subject to the nonallowance of the linking claim(s), claim 65. Upon the allowance of the linking claim(s), the restriction requirement as to the linked groups shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

13. Groups I-XXII represent patentably distinct products. Groups I-XXII represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, the sequences in Groups I and IV do not overlap at all. Furthermore, the rest of the Groups are also structurally distinct with different physical and chemical properties. In addition, art anticipating or rendering obvious each Group i.e., Groups I-XXII would not render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will

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support separate patents. Consequently, Groups I-XXII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

14. Groups XXIV-XXXXII represent patentably distinct methods. The methods are different because they use different steps, require different reagents and/or will produce different results. For example, Group XXIV represents a method for producing a composition whereas Group XXXXI represents a method of treating or preventing a condition consisting of HIV infection, cancer, wasting, and hematopoietic deficiency. These methods require different reagents and/or method steps and would produce different results. Consequently, examining Groups XXIV-XXXXII together will require searching different reagents, different method steps, and different products, which in most cases will fall under many different US classification numbers. Therefore, searching Groups XXIV-XXXXII together would represent an undue search burden. In addition, art anticipating or rendering obvious each Group i.e., Groups XXIV-XXXXII would not render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics (a demonstrated ability to produce a composition does not render obvious an ability to treat an HIV infection). Each group will support separate patents. Consequently, Groups XXIV-XXXXII have different issues regarding patentability and enablement and represent patentably distinct subject matter.

15. Groups XXIII and XXXXIII-LIV represent patentably distinct compositions. Groups XXIII and XXXXIII-LIV represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For

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example Group XXXXVIII requires the use and production of cyclic peptides that Group XXXXVII does not require. Likewise the other Groups require different reagents that render each Group patentably distinct. In addition, art anticipating or rendering obvious each Group i.e., Groups XXIII and XXXXIII-LIV would not render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Each group will support separate patents. Consequently, Groups XXIII and XXXXIII-LIV have different issues regarding patentability and enablement and represent patentably distinct subject matter.

16. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

17. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

18. If applicant elects any one of the Groups outlined above, applicant is required to elect from the following patentably distinct species.

Species of protein or peptide

Applicant must elect for the purposes of search, a single species of protein or peptide wherein the sequence of said protein or peptide is provided including any non-classical amino acids and/or D-amino acids, N-acetylation or C-terminal amide groups, along with

any branched or circularized architecture. Applicant must also indicate which claims read on the single elected species of protein or peptide.

19. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

20. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

21. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

22. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after



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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

23. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

24. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

25. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

26. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the



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merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.  
August 26, 2002

BENNETT CELSA  
PRIMARY EXAMINER



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